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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/096,648	06/12/1998	GYULA HADLACZKY	24601-402A	2049

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EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/096,648

Applicant(s)

HADLACZKY ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89 and 93-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 98 and 99 is/are allowed.
- 6) ☒ Claim(s) 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89, 93-97 and 100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Note that the Examiner of record has changed. The Examiner of record is now Thaian N. Ton of Art Unit 1632.

Applicants' Amendment, filed 9/7/01, Paper No. 23, has been entered.

Claims 40, 41, 90-92 and 101-105 have been cancelled.

Claims 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89, 93-100 are pending and under current examination.

Rejections made of record in the prior Office action (Paper No. 18) not made of record in the instant Office action have been withdrawn in view of Applicants' arguments, amendments to the claims and/or the Perez Declaration under 1.132.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89 and 93-97 and 100 are maintained for the reasons advanced on pages 2-5 of the prior Office Action, mailed 3/1/01, Paper No. 18.

**However, please note** that the Perez Declaration under 37 CFR 1.132 filed February 1, 2001 (Paper No. 17) is sufficient with regard to the following enabled scope: a method for producing a transgenic non-human mammal comprising introducing in a female non-human mammal an ovum comprising a SATAC, wherein the ovum

develops into a zygote or embryo; and allowing the embryo to develop into a transgenic non-human mammal comprising said SATAC; and a method for producing a transgenic mouse comprising introducing mouse embryonic stem cells comprising a SATAC into a mouse embryo and introducing said embryo into a female mouse; and allowing the embryo to develop into a transgenic mouse comprising said SATAC.

Claims 32, 43, 44, 73, 74, 82, 93, 95, and 96 recite the term, "cell(s)". Dependent claims further distinguish the particular "cell(s)". As such, all claims have been included in this rejection, as the claims are not complete because the claims are missing critical steps dependent upon the source "cell(s)". (See scope of enablement, above). For example, if the cell is an oocyte, an unfertilized oocyte will not develop into an animal. Furthermore, direct introduction of a germ cell, which is not a fertilized ovum into a female animal, is not sufficient for development of any animal. Applicants indicate that exemplary cells for use in the claimed method are referred to in the application (p. 10, 3<sup>rd</sup> paragraph for Applicants' response) and further, Applicants argue that the specification refers to procedures for introducing exogenous genetic material into the pronucleus of a mammalian zygote or fertilized oocyte by microinjection and additionally, that nuclear transfer methods would have been readily available to produce the claimed transgenic non-human mammals. Applicants argue that with respect to nuclear transfer, an unfertilized oocyte would develop into an animal. Applicants direct the Examiner to particular examples (e.g. Campbell *et al.*, (1996) Nature), but do not provide the references and thus, will not be considered by the Examiner. Additionally, the specification broadly discusses the generation of transgenic animals (see p. 34, part a) by methods such as microinjection, however, the specification does not contemplate

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the use of nuclear transfer methods to generate the transgenic animals of the claimed invention. It is noted that nuclear transfer methods require the correct chromosomal number or ploidy, which would not be present if a SATAC was present. Therefore, as stated above, it is maintained that because an ovum comprising a SATAC, wherein the ovum develops into a zygote or embryo, are not described in the claims, the claims are missing critical steps.

With regard to claims 82-89, note that the claims are only enabled for a methods of producing a transgenic non-human embryo (see enablement above).

Furthermore, with regard to those claims which are directed to "embryonic stem cells" and are not limited to "mouse embryonic stem cells," it is maintained that the art-recognized embryonic stem cells contributes to the germ line of the animal and that only embryonic stem cells isolated from the mouse have been established in the art at the time of the effective filing of the instant application (see p. 3 of the prior Office Action, Paper No. 18 and pp. 4-5 of the Office Action mailed 6/21/00, Paper No. 12). Applicants allege on p. 9, 1<sup>st</sup> paragraph of the response that Applicant notes that only claim 33 recites the phrase, "stem cell," which has been amended to recite, "mouse stem cell." However, it is noted that not all mouse stem cells would develop into a transgenic mouse, and that only mouse embryonic stem cells would be capable of development into such an animal.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89 and 93-96 and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is maintained that the claims, as written are incomplete. See p. 5 of Prior Office Action (Paper No. 18). Applicants argue that the essential steps of the method claims have been provided in the currently pending claims (see p. 13), however, Applicants' amendments to the claims fail to overcome this rejection. For example, Claims 32, 43, 44, 73, 74, 82, 93, 95, and 96 recite the term, "cell(s)". Dependent claims further distinguish the particular "cell(s)". As such, all claims have been included in this rejection, as the claims are not complete because the claims are missing critical steps dependent upon the source "cell(s)". (See scope of enablement, above). For example, if the cell is an oocyte, an unfertilized oocyte will not develop into an animal. Furthermore, direct introduction of a germ cell, which is not a fertilized ovum into a female animal, is not sufficient for development of any animal. See enabled scope above.

### **Conclusion**

Claims 98 and 99 appear to be allowable.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Karen Hauda, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-6608. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

TNT

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